1. PRODUCT AND COMPANY IDENTIFICATION

Company

Arkema Inc.
900 First Avenue
King of Prussia, Pennsylvania 19406

Functional Additives

Customer Service Telephone Number: (800) 331-7654
(Monday through Friday, 8:00 AM to 5:00 PM EST)

Emergency Information

Transportation: CHEMTREC: (800) 424-9300
(24 hrs., 7 days a week)
Medical: Rocky Mountain Poison Center: (866) 767-5089
(24 hrs., 7 days a week)

Product Information

Product name: LUPEROX® 331M80
Synonyms: Peroxyketal
Molecular formula: Complex mixture
Chemical family: Organic peroxide - peroxyketals
Product use: Initiator

2. HAZARDS IDENTIFICATION

Emergency Overview
Color: Clear - colourless
Physical state: liquid
Odor: Smelling of camphor

***Classification of the substance or mixture:**
Flammable liquid., Category 3, H226
Organic peroxides, Type C, H242
Aspiration hazard, Category 1, H304
Chronic aquatic toxicity, Category 3, H412

*For the full text of the H-Statements mentioned in this Section, see Section 16.

GHS-Labelling

Hazard pictograms:

Signal word: **Danger**

Hazard statements:

H226 : Flammable liquid and vapour.
H242 : Heating may cause a fire.
H304 : May be fatal if swallowed and enters airways.
H412 : Harmful to aquatic life with long lasting effects.

Supplemental Hazard Statements:

Organic peroxide. Hazardous decomposition may occur.

Precautionary statements:

Prevention:

P210 : Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P220 : Keep/Store away from clothing/ combustible materials.
P233 : Keep container tightly closed.
P234 : Keep only in original container.
P240 : Ground/bond container and receiving equipment.
P241 : Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P242 : Use only non-sparking tools.
P243 : Take precautionary measures against static discharge.
P273 : Avoid release to the environment.
P280 : Wear protective gloves/ eye protection/ face protection.

Response:

P301 + P310 : IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
P303 + P361 + P353 : IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P331 : Do NOT induce vomiting.
P370 + P378 : In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage:

P405 : Store locked up.
P410 : Protect from sunlight.
P411 + P235 : Maximum storage temperature is specified on label and in section 7 of SDS. Keep cool.
P420 : Store away from other materials.

Disposal:

P501 : Dispose of contents/ container to an approved waste disposal plant.

Supplemental information:

Potential Health Effects:
Prolonged or repeated skin contact may cause defatting resulting in drying, redness and rash. Symptoms of aspiration may include increased breathing and heart rate, coughing and related signs of respiratory distress. May also cause: chest discomfort, accumulation of fluid in the lungs, (severity of effects depends on extent of exposure).

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Peroxide, cyclohexylidenebis[(1,1-dimethylethyl)	3006-86-8	>= 78 - <= 80 %	H241, H413
Naphtha (petroleum), hydrotreated heavy	64742-48-9	< 22 %	H315, H411, H336, H304, H224
Naphtha (petroleum), heavy alkylate	64741-65-7	< 22 %	H226, H304, H413

**For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

Inhalation:
If inhaled, remove victim to fresh air.

Skin:
In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:
Immediately flush eye(s) with plenty of water.

Ingestion:
If swallowed, DO NOT induce vomiting. Call a physician or Poison Control Center immediately. If vomiting occurs, have person lean forward. Never give anything by mouth to an unconscious person.

5. FIREFIGHTING MEASURES

Extinguishing media (suitable):

Water spray, Foam, Dry chemical

Extinguishing media (unsuitable):
Water may be ineffective., Do not use a solid water stream as it may scatter and spread fire.

Protective equipment:
Fire fighters and others who may be exposed to products of combustion should wear full fire fighting turn out gear (full Bunker Gear) and self-contained breathing apparatus (pressure demand / NIOSH approved or equivalent).

Further firefighting advice:
Fight fire with large amounts of water from a safe distance.
Cool closed containers exposed to fire with water spray.
Closed containers of this material may explode when subjected to heat from surrounding fire.
After a fire, wait until the material has cooled to room temperature before initiating clean-up activities.
Do not allow run-off from fire fighting to enter drains or water courses.
Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:
Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.
When burned, the following hazardous products of combustion can occur:
Carbon oxides
Hazardous organic compounds

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, Emergency procedures, Methods and materials for containment/clean-up:
Prevent further leakage or spillage if you can do so without risk. Evacuate area of all unnecessary personnel. Ventilate the area. Eliminate all ignition sources. Avoid generation of vapors. Contain and collect spillage with non-combustible absorbent material such as sodium bicarbonate, sodium carbonate, calcium carbonate, clean sand or non-acidic clay and then wet down (dampen) the mixture with water. DO NOT USE peat moss. Sweep or scoop up using non-sparking tools and place into suitable properly labeled containers for prompt disposal. The sweepings should be wetted down further with water. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits.

Protective equipment:
Appropriate personal protective equipment is set forth in Section 8.

7. HANDLING AND STORAGE

Handling

General information on handling:
Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.
Do not taste or swallow.
Avoid breathing vapor or mist.
Keep away from heat, sparks and flames.
No smoking.
Use only with adequate ventilation.
Wash thoroughly after handling.
Prevent product contamination.
Keep container tightly closed and away from combustible materials.
Keep only in the original container.
Check that all equipment is properly grounded and installed to satisfy electrical classification requirements.
Container hazardous when empty.
Follow label warnings even after container is emptied.
RESIDUAL VAPORS MAY EXPLODE ON IGNITION.
DO NOT CUT, DRILL, GRIND, OR WELD ON OR NEAR THIS CONTAINER.
Do not reuse container as it may retain hazardous product residue.
Improper disposal or reuse of this container may be dangerous and/or illegal.
Emptied container retains vapor and product residue.

Storage

General information on storage conditions:
Keep container closed when not in use. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Outside or detached storage is preferred. Store in well ventilated area away from heat and sources of ignition such as flame, sparks and static electricity. Ensure that all storage and handling equipment is properly grounded and installed to satisfy electrical classification requirements. Store out of direct sunlight in a cool well-ventilated place. Store in original container. Store away from combustibles and materials to avoid. Static electricity may accumulate when transferring material. All metal and groundable storage containers, including but not limited to drums, cylinders, Returnable Intermodal Bulk Containers (RIBCs) and Class C Flexible Intermodal Bulk Containers (FIBCs) must be bonded and grounded during filling and emptying operations. Observe all federal, state and local regulations and National Fire Protection Association (NFPA) Codes which pertain to the specific local conditions of storage and use, including OSHA 29 CFR 1910.106 and NFPA 30, 70, 77, and 497. Refer also to National Fire Protection Association (NFPA) Code 400, Hazardous Materials Code.

Storage stability – Remarks:
Follow the recommended storage temperatures provided in this Section in order to maintain stability and oxygen content.

Storage incompatibility – General:
Store separate from:

Strong acids

Strong bases

Strong oxidizing agents

Reducing agents

Accelerators

Friedel - Crafts reaction catalyst

Brass

Copper

Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Temperature tolerance – Do not store above:
100 °F (38 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Naphtha (petroleum), hydrotreated heavy (64742-48-9)

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

PEL:	100 ppm (400 mg/m3)

Only those components with exposure limits are printed in this section. Limits with skin contact designation above have skin contact effect. Air sampling alone is insufficient to accurately quantitate exposure. Measures to prevent significant cutaneous absorption may be required. Limits with a sensitizer designation above mean that exposure to this material may cause allergic reactions.

Engineering controls:
Investigate engineering techniques to reduce exposures below airborne exposure limits or to otherwise reduce exposures. Provide ventilation if necessary to minimize exposures or to control exposure levels to below airborne exposure limits (if applicable see above).If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment.

Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems.

Respiratory protection:
Avoid breathing vapor or mist. Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Consult respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Skin protection:
Minimize skin contamination by following good industrial hygiene practice. Wearing protective gloves is recommended. Wash hands and contaminated skin thoroughly after handling.

Eye protection:
Use good industrial practice to avoid eye contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	Clear - colourless
Physical state:	liquid
Odor:	Smelling of camphor
Odor threshold:	No data available
Flash point	The flashpoint of this product is greater than the Self Acceleration Decomposition Temperature (SADT).
Auto-ignition temperature:	No data available
Lower flammable limit (LFL):	No data available
Upper flammable limit (UFL):	No data available
pH:	No data available
Density:	0.89 g/cm3 (77 °F (25 °C))
Specific Gravity (Relative density):	0.89 (77 °F(25 °C))
Vapor pressure:	No data available
Vapor density:	No data available
Boiling point/boiling range:	Decomposes before boiling. Rate of decomposition increases with rising temperature.
Melting point/range:	5 °F (-15 °C)
Freezing point:	5 °F (-15 °C)
Evaporation rate:	No data available
Solubility in water:	insoluble
Viscosity, dynamic:	No data available
Oil/water partition coefficient:	No data available
Self-Accelerating Decomposition Temperature (SADT):	estimated 149 °F (65 °C) 35 pound container

Thermal decomposition No data available

Active oxygen content: 9.59 - 9.83 %

Flammability: See GHS Classification in Section 2

10. STABILITY AND REACTIVITY

Stability:
This material is chemically unstable and should only be handled under specified conditions. See HANDLING AND STORAGE section of this SDS for specified conditions.

Hazardous reactions:
Hazardous polymerization does not occur.

Materials to avoid:
Strong acids
Strong bases.
Strong oxidizing agents
Reducing agents
Accelerators
Friedel - Crafts reaction catalyst
Brass
Copper
Iron
For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Conditions / hazards to avoid:
See HANDLING AND STORAGE section of this SDS for specified conditions. SADT - Self Accelerating Decomposition Temperature. Lowest temperature at which the tested package size will undergo a self-accelerating decomposition reaction. This reaction will generate flammable vapors which may autoignite. The length of time to generate a decomposition reaction, after the SADT has been reached or exceeded, is dependent upon how much the SADT has been exceeded and the length of time needed for the reaction exotherm (heat spike from increasing decomposition rate) to initiate a rapid decomposition reaction. Typically, SADT is inversely proportional to package size. Larger packages will have a lower SADT due to smaller ratio to heat transfer area to volume of product.

Hazardous decomposition products:

Temperatures at or above SADT can result in the release of hazardous decomposition products which are flammable and may autoignite.
Thermal decomposition giving flammable and toxic products:
Carbon oxides
Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

Data on this material and/or its components are summarized below.

Data for Peroxide, cyclohexylidenebis[(1,1-dimethylethyl) (3006-86-8)

Acute toxicity

Oral:
Practically nontoxic. (rat) LD50 = 16,653 mg/kg. (65 %)

Dermal:
No deaths occurred. (rat) LD0 > 2,000 mg/kg. (50 %)

Inhalation:
No deaths occurred. (rat) 4 h LC0 = 207.2 mg/l. (65 %) (aerosol)

Skin Irritation:
Causes mild skin irritation. (rabbit) Irritation Index: 1,2/8,0. (24 h) (65 %)

Repeated dose toxicity
Repeated exposure oral administration to rat / affected organ(s): kidney / reduced body weight

Genotoxicity

Assessment in Vitro:
No genetic changes were observed in laboratory tests using: bacteria, human cells, animal cells

Reproductive effects
Reproductive/Developmental Effects Screening Assay. oral (rat) / No effects on fertility

Data for Naphtha (petroleum), hydrotreated heavy (64742-48-9)

Acute toxicity

Oral:
No deaths occurred. (rat) LD0 > 5,000 mg/kg.

Dermal:
May be harmful in contact with skin. (rabbit) LD50 > 2,000 mg/kg.

Inhalation:
No deaths occurred. (rat) 4 h LC0 > 5 mg/l. (vapour)

Specific target organ toxicity - single exposure:
May cause drowsiness or dizziness. (central nervous system)

Skin Irritation:
Causes skin irritation. (rabbit)

Eye Irritation:
Causes mild eye irritation. (rabbit)

Skin Sensitization:
Not a sensitizer. Repeated skin exposure. (guinea pig) No skin allergy was observed (data for a similar material)

Repeated dose toxicity
Subchronic inhalation administration to rat / affected organ(s): kidney / signs: changes in organ weights, changes in organ structure or function, hyaline droplet nephropathy / (not considered relevant

in humans)

Repeated oral administration to rat / affected organ(s): kidney / signs: changes in organ weights, changes in organ structure or function, hyaline droplet nephropathy / (not considered relevant in humans)

Genotoxicity

Assessment in Vitro:
No genetic changes were observed in laboratory tests using: bacteria, animal cells

Genotoxicity

Assessment in Vivo:
No genetic changes were observed in laboratory tests using: mice

Developmental toxicity

Exposure during pregnancy. Inhalation (rat) / No birth defects were observed.

Other information
The information presented is from representative materials in this chemical class. The results may vary depending on the test substance.

Aspiration hazard
May be fatal if swallowed and enters airways.

Human experience
Inhalation:
Cardio-vascular system: Irregular cardiac activity, rapid heart beat. (repeated or prolonged exposure) (effects associated with substance abuse) (data for similar materials)

Human experience
Skin contact:
Skin: No skin allergy was observed. (studied using human volunteers) Prolonged skin contact may defat the skin and produce dermatitis.

Data for Naphtha (petroleum), heavy alkylate (64741-65-7)

Acute toxicity

Oral:
Practically nontoxic. (rat) LD50 > 7,600 mg/kg.

Dermal:
No deaths occurred. (rabbit) LD0 > 3,040 mg/kg.

Inhalation:
No deaths occurred. (rat) 4 h LC0 > 9.3 mg/l. (saturated vapor)

Skin Irritation:
Causes mild skin irritation. (rabbit) Irritation Index: 2.4/8.0. (4 h)

Skin Sensitization:
Not a sensitizer. Guinea pig maximization test. (guinea pig) No skin allergy was observed

Repeated dose toxicity
Repeated inhalation administration to rat / affected organ(s): kidney / signs: damage, changes in organ structure or function, hyaline droplet nephropathy / (not considered relevant in humans)

Other information
The information presented is from representative materials in this chemical class. The results may vary depending on the test substance.

Aspiration hazard
May be fatal if swallowed and enters airways.

Human experience
Inhalation:
Cardio-vascular system: Irregular cardiac activity, rapid heart beat. (repeated or prolonged exposure) (effects associated with substance abuse) (data for similar materials)

Human experience
Skin contact:
Skin: Prolonged skin contact may defat the skin and produce dermatitis.

12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway
Data on this material and/or its components are summarized below.

Data for Peroxide, cyclohexylidenebis[(1,1-dimethylethyl) (3006-86-8)

Biodegradation:
Not readily biodegradable. (Modified Sturm Test, 28 d) biodegradation 5 %

Octanol Water Partition Coefficient:
log Pow > 6.5

Data for Naphtha (petroleum), hydrotreated heavy (64742-48-9)

Biodegradation:
Readily biodegradable. (28 d) biodegradation 77 %

Octanol Water Partition Coefficient:
log Pow = 2.1 - 6.5 (calculated)

Data for Naphtha (petroleum), heavy alkylate (64741-65-7)

Biodegradation:
Not readily biodegradable. (28 d) biodegradation 8 - 22 %

Potential to bioaccumulate

Octanol Water Partition Coefficient:
log Pow = 2.8 - 6 (calculated) (data for a similar material)

Ecotoxicology
Data on this material and/or its components are summarized below.

Data for Peroxide, cyclohexylidenebis[(1,1-dimethylethyl) (3006-86-8)

Aquatic toxicity data:
No effect up to the limit of solubility. Danio rerio (zebra fish) 96 h LC50 > 0.64 mg/l

Aquatic invertebrates:
No effect up to the limit of solubility. Daphnia (water flea) 48 h EC50 > 0.6 mg/l

Algae:
No effect up to the limit of solubility. Pseudokirchneriella subcapitata (green algae) 72 h EC50 > 0.5 mg/l

Microorganisms:
No effect up to the limit of solubility. Activated sludge 3 h EC50 > 20 mg/l

Data for Naphtha (petroleum), hydrotreated heavy (64742-48-9)

Aquatic toxicity data:
Toxic. Pimephales promelas (fathead minnow) 96 h LL50 = 8.2 mg/l

Aquatic invertebrates:
Toxic. Daphnia magna (Water flea) 48 h EL50 = 4.5 mg/l (nominal concentrations reported, Water accommodated fraction was tested.)

Algae:
Toxic. Pseudokirchneriella subcapitata (green algae) 72 h EL50 = 3.1 mg/l (nominal concentrations reported, Water accommodated fraction was tested.)

Chronic toxicity to aquatic invertebrates:
Daphnia magna (Water flea) 21 d NOEC (reproduction) = 2.6 mg/l (Water accommodated fraction was tested.) (Nominal concentration)

Data for Naphtha (petroleum), heavy alkylate (64741-65-7)

Aquatic toxicity data:
No effect up to the limit of solubility. Fish 96 h LL50 > 1,000 mg/l
No effect up to the limit of solubility. Carassius auratus (goldfish) 24 h

Aquatic invertebrates:
No effect up to the limit of solubility. Daphnia magna (Water flea) 48 h EL50 > 1,000 mg/l

Algae:
No effect up to the limit of solubility. Algae 72 h EL50 > 1,000 mg/l

13. DISPOSAL CONSIDERATIONS

Waste disposal:
Dilution followed by incineration is the preferred method. Dilution ratio of 10:1 in a clean, compatible, combustible solvent (i.e., Fuel Oil #2, mineral oil) will reduce reactivity hazard during incineration and transportation. Dispose of in accordance with federal, state and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste disposal requirements may be more restrictive or otherwise different from federal laws and regulations.

Take appropriate measures to prevent release to the environment.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number	:	3103
Proper shipping name	:	Organic peroxide type C, liquid, sample
Technical name	:	(1,1-Di-(tert-butylperoxy) cyclohexane, >52-80%)
Class	:	5.2
Packaging group	:	II
Marine pollutant	:	no

International Maritime Dangerous Goods Code (IMDG)

UN Number	:	3103
Proper shipping name	:	ORGANIC PEROXIDE TYPE C, LIQUID, SAMPLE
Technical name	:	(1,1-DI-(tert-BUTYLPEROXY) CYCLOHEXANE, >52-80%)
Class	:	5.2
Marine pollutant	:	no

15. REGULATORY INFORMATION

Chemical Inventory Status

EU. EINECS	EINECS	Conforms to
United States TSCA Inventory	TSCA	The components of this product are all on the TSCA Inventory.
Canadian Domestic Substances List (DSL)	DSL	All components of this product are on the Canadian DSL
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Conforms to
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Does not conform
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Does not conform
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Conforms to
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Conforms to
Australia Inventory of Chemical Substances (AICS)	AICS	Conforms to

United States – Federal Regulations

SARA Title III – Section 302 Extremely Hazardous Chemicals:

The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:
Acute Health Hazard, Fire Hazard, Reactivity Hazard

SARA Title III – Section 313 Toxic Chemicals:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):

Chemical Name	CAS-No.	Reportable quantity
2-Propanol, 2-methyl-	75-65-0	100 lbs
Peroxide, bis(1,1-dimethylethyl)	110-05-4	100 lbs
Cyclohexanone	108-94-1	5000 lbs

United States – State Regulations

New Jersey Right to Know

No components are subject to the New Jersey Right to Know Act.

Pennsylvania Right to Know

Chemical Name	CAS-No.
Peroxide, cyclohexylidenebis[(1,1-dimethylethyl)	3006-86-8
Naphtha (petroleum), hydrotreated heavy	64742-48-9
Naphtha (petroleum), heavy alkylate	64741-65-7

California Prop. 65
This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive defects.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

H224 Extremely flammable liquid and vapour.
H226 Flammable liquid and vapour.
H241 Heating may cause a fire or explosion.
H242 Heating may cause a fire.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H336 May cause drowsiness or dizziness.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.
H413 May cause long lasting harmful effects to aquatic life.

Miscellaneous:

Other information:	Refer to National Fire Protection Association (NFPA) Codes 30, 70, 77, and 497 and OSHA 29 CFR 1910.106, for safe handling.

Latest Revision(s):

Reference number:	000000034149
Date of Revision:	10/18/2015
Date Printed:	11/29/2016

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Arkema has implemented a Medical Policy regarding the use of Arkema products in Medical Devices applications that are in contact with the body or circulating bodily fluids (http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices , and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.
It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies) It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.